



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Melissa Grace, Michael Slivka, Thomas G. Ferro, Vivek N. Shenoy, Alonzo D. Cook, and Scott Bruder

Application No.: 10/723,250 Group Art Unit: 1617
Filed: November 26, 2003 Examiner: Williams, Leonard M.
Confirmation No.: 6059
Title: LOCAL INTRAOSSEOUS ADMINISTRATION OF BONE FORMING AGENTS AND ANTI-RESORPTIVE AGENTS, AND DEVICES THEREFOR

CERTIFICATE OF MAILING OR TRANSMISSION	
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March 23, 2006	<i>Linda M. Byrnes</i>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references are enclosed. [B9-B19 and C43-C116]
 - ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

March 23, 2006

PTO-1449 REPRODUCED

**SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

March 20, 2006

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
3518.1024-000

APPLICATION NO.
10/723,250

FIRST NAMED INVENTOR
Thomas M. DiMauro

FILING DATE
November 26, 2003

EXAMINER
Williams, Leonard M.

CONFIRMATION NO.
6059

GROUP
1617



U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A21	4,427,649	01-24-1984	Dingle, <i>et al.</i>
	A22	5,095,037	03-10-1992	Iwamitsu, <i>et al.</i>
	A23	5,368,841	11-29-1994	Trauner, <i>et al.</i>
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	A25	5,833,984	11-10-1998	Eibl, <i>et al.</i>
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	A27	6,294,170	09-25-2001	Boone, <i>et al.</i>
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	A29	6,340,369 B1	01-22-2002	Ferree
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	A31	US 2001/0006948	07-05-2001	Kang, <i>et al.</i>
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	A35	US 2002/0032155 A1	03-14-2002	Ferree
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	A38	US 2003/0134792 A1	07-17-2003	Pike, <i>et al.</i>
	A39	US 2004/0193274 A1	09-30-2004	Trieu
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PTO-1449 REPRODUCED SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION March 20, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3518.1024-000		APPLICATION NO. 10/723,250	
	FIRST NAMED INVENTOR Thomas M. DiMauro		FILING DATE November 26, 2003	
	EXAMINER Williams, Leonard M.	CONFIRMATION NO. 6059	GROUP 1617	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C43	Abstracts of the North American Spine Society 17 Annual Meeting, Montreal, Canada, October 29 through November 2, 2002, <i>The Spine Journal</i> 2(5 Suppl):49S-50S (2002).
C44	Ahn, N. U., <i>et al.</i> , "Effect of Nutrient Concentration and OP-1 on the Metabolism of Intervertebral Disc: <i>In Vitro</i> Organ Culture Study," 28, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine, Vancouver, Canada (May 2003).
C49	Alini, M., <i>et al.</i> , "A Biological Approach in Treating Disc Degeneration: Not for Today, but Maybe for Tomorrow," <i>European Spine Journal</i> , 11(Suppl 2):S215-S220 (2002).
C46	Andonopoulos, A. P., <i>et al.</i> , "Intra-articular Anti-Tumor Necrosis Factor α Antibody in Recalcitrant Arthritis of Behçet's Disease," <i>Clinical and Experimental Rheumatology</i> 21(4 Suppl 30):S-57-S58 (July-August 2003).
C49	Aoki, Y., <i>et al.</i> , "Local Application of Disc-Related Cytokines on Spinal Nerve Roots," <i>Spine</i> 27(15): 1614-1617 (2002).
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C49	Ariga, K., <i>et al.</i> , "Mechanical Stress-Induced Apoptosis of Endplate Chondrocytes in Organ-Cultured Mouse Intervertebral Discs," <i>Spine</i> , 28(14):1528-1533 (2003).
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C53	Bringman, T.S., <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
C54	Brown, K., <i>et al.</i> , "Gelatin/Chondroitin 6-Sulfate Microspheres for the Delivery of Therapeutic Proteins to the Joint," <i>Arthritis. & Rheum.</i> , 41(12):2185-2195 (1998).
C60	Burke, J. G., <i>et al.</i> , "Human Nucleus Pulposus Secretes Transforming Growth Factor Beta-1 and Basic Fibroblast Growth Factor," 189, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C56	Burke, J.G., <i>et al.</i> , "Intervertebral Discs Which Cause Low Back Pain Secrete High Levels of Proinflammatory Mediators," <i>J. Bone Joint Surg. [Br]</i> , 84-B, 196-201 (2002).
C57	Cardone, D.A., and Tallia, A.F., "Diagnostic and Therapeutic Injection of the Hip and Knee," <i>Am. Fam. Physician</i> , 67(10):2147-2152 (2003).
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C62	Diwan, A.D., <i>et al.</i> , "Current Concepts in Intervertebral Disk Restoration," <i>Tissue Engineering in Orthopedic Surgery</i> , 31(3):453-464 (2000).

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C73	Imai, Y., <i>et al.</i> , "Effect of Recombinant Human Osteogenic Protein-1 on Extracellular Matrix Metabolism by Human Annulus Fibrosus and Nucleus Pulposus Cells," 205, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C74	Imai, Y., <i>et al.</i> , "The Quantification of Cytokine-Induced Matrix Catabolism in Tissue Engineered Intervertebral Discs," 67, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C75	Inui, Y., <i>et al.</i> , "Fas-Ligand Expression on Nucleus Pulposus Cells Begins in Developing Embryo," 42, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C76	Johnson, W.H., <i>et al.</i> , "Collagenase Inhibitors: Their Design and Potential Therapeutic Use," <i>J. Enzyme Inhib.</i> , 2:1-22 (1987).
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C78	Kato, H., <i>et al.</i> , "The Effect of IL-1 on the Rabbit Intervertebral Disc In Vivo," 199, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C79	Kawakami, M., <i>et al.</i> , "Possible Mechanism of Painful Radiculopathy in Lumbar Disc Herniation," <i>Clin. Orthop.</i> , 351:241-251(1998).
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C82	Korhonen, T., <i>et al.</i> , "Efficacy of Infliximab for Disc Herniation-Induced Sciatica One-Year Follow-Up," 14, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C83	Kwon, U-H., <i>et al.</i> , "Dexamethsone Stimulates Cellular Proliferation While Downregulates Matrix Synthesis in Intervertebral Disc Cells," 29, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
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C85	LaVan, D. A., <i>et al.</i> , "Small-scale Systems for <i>in vivo</i> Drug Delivery," <i>Nature, Biotechnology</i> , 21(10):1184-1191 (2003).
C86	Lee, C. S., <i>et al.</i> , "A Single Period of Hyperphysiologic Stretch Induces IL-6, TGF-beta and Cell Proliferation in Anulus Fibrosus Cells," 215, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C87	Lehman, T. J. A., <i>et al.</i> , "Thalidomide Therapy for Recalcitrant Systemic Onset Juvenile Rheumatoid Arthritis," <i>J. Pediatrics</i> , 140(1):125-127 (2002).
C88	Le Maitre, C. L., <i>et al.</i> , "Expression of the IL-1 Family in Human Intervertebral Disc," 217, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
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C90	Le Visage, C., <i>et al.</i> , "Interaction of Human Mesenchymal Stem Cells with Disc Cells: Changes in Biosynthesis of Extracellular Matrix," 25, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).

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C91	Li, J., <i>et al.</i> , "The Effects of Bone Morphogenetic Protein 2 (BMP-2) and Cartilage-Derived Morphogenetic Protein 2 (CDMP-2) on Aggrecan Gene Expression in Chondrocytes," 30, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
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C95	Meijer, H., <i>et al.</i> , "The Production of Anti-Inflammatory Cytokines in Whole Blood by Physico-Chemical Induction," <i>Inflamm. Res.</i> , 52: 404-407 (2003).
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C97	Sakai, D., <i>et al.</i> , "Autologous Transplantation of Mesenchymal Stem Cells for Disc Repair," 24, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C98	Molloy, T., <i>et al.</i> , "The Roles of Growth Factors in Tendon and Ligament Healing," <i>Sports Med.</i> , 33(5): pp.381-394 (2003).
C99	Nikas, S. N., <i>et al.</i> , "Treatment of Resistant Rheumatoid Arthritis by Intra-Articular Infliximab Injections: A Pilot Study," <i>Ann. Rheum. Dis.</i> , downloaded from ard.bmjournals.com on 2 November 2005, www.annrheumdis.com 63: 102-103 (2004).

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C100	Ohtori, S., <i>et al.</i> , "TNF- α and TNF- α Receptor 1 Upregulation in GLIA and Neurons After Nerve Injury. Studies in Murine DRG and Spinal Cord," <i>13, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
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C102	Richardson, S., <i>et al.</i> , "Human Bone Marrow Mesenchymal Stromal Cells as a Source of Chondrocytes for Treatment of Intervertebral Disc Degeneration," <i>27, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
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C104	Schatteman, L., <i>et al.</i> , "Treatment of Refractory Inflammatory Monoarthritis in Ankylosing Spondylitis by Intraarticular Injection of Infliximab," <i>J. Of Rheum.</i> , 33:1:82-85 (2006).
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C106	Stern, S., <i>et al.</i> , "Human Intervertebral Disc Cell Culture for Disc Disorders," <i>Clin. Orthop.</i> , 419:238-244 (2004).
C107	Takada, T., <i>et al.</i> , "IL-6 Production was Upregulated by Interaction Between Disc Tissue and Macrophages," <i>41, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C108	Takegami, K. <i>et al.</i> , "Osteogenic Protein-1 Enhances Matrix Replenishment by Intervertebral Disc Cells Previously Exposed to Interleukin-1," <i>Spine</i> , 27(12):1318-1325 (2002).

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EXAMINER	DATE CONSIDERED
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